PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Roger D.A. Lipman
Application No.	: 10/069,214
Filed	: February 22, 2002
Title	: CYCLODEXTRIN-CONTAINING PRESSURE-SENSITIVE ADHESIVES (As amended)
Grp./Div.	: 1615
Examiner	: Ghali, Isis A.D.
Docket No.	: 47915/JDC/A23

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: 9/3/04 Ann M. Baker
(Date of Deposit)

DECLARATION OF ROGER D.A. LIPMAN
SUBMITTED UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Post Office Box 7068
Pasadena, CA 91109-7068
September 3, 2004

Sir:

Pursuant to 37 CFR § 1.132, I, Roger D.A. Lipman, Ph.D., hereby declare:

1. I am the inventor named on the above-reference patent application. Unless otherwise indicated, I have personal knowledge of the facts recited below, and if called to testify I could and would testify competently thereto.

2. My background and professional experience are described in my resume, a true and correct copy of which is attached hereto as Exhibit A. Briefly, I received a Ph.D. in Physical Polymer Chemistry from Cambridge University, England in 1963. My doctoral research focused on the elucidation of the reaction mechanism of heterogeneous polymerization of α-olefins. From 1963-4 I held a National Science Foundation Post-Doctoral fellowship at New York State College of Environmental Science and Technology at Syracuse NY, where I worked on anionic polymerization .

From 1964 through 1973 I was employed by the then Ciba-Geigy Corporation in Ardsley, NY. I led projects to develop polymeric viscosity index improvers and pressure-sensitive adhesives,

both derived from poly-α-olefins. A synopsis of some of this work is provided in the book Pressure Sensitive Adhesives, Formulations and Technology, by L.F. Martin, Noyes Data Corp, (1974), where the work with adhesives is detailed on pp. 90-92.

I was Manager of the polymer characterization laboratory at Ciba-Geigy.

From 1973-80 I worked for Johnson & Johnson Inc. in New Brunswick NJ, where I was Manager, Adhesive Products, a group of 20+ people focused on product development and technical support of all J&J adhesive tape and bandage products.

From 1981-2 I was Director of Research and Development, ConvaTec Division, Bristol-Myers Squibb in East Brunswick, NJ, where I was responsible for the total product development effort in hydrocolloid adhesive-based ostomy and chronic wound products. My group developed DuoDerm, the first hydrocolloid dressing, a product that revolutionized management of chronic wounds such as venous ulcers and pressure sores.

From 1983 through 1985 I was Director of Research and Development at Franklin Medical Ltd, High Wycombe, England, a manufacturer of anaesthesia, urology and ostomy products.

From 1985-96 I was Managing Director of my own company, MediQuest Products Ltd, in Horsham, England. MediQuest manufactured and developed hydrocolloid-based products that were supplied to medical device OEMs, among which Sherwood Medical (now part of Tyco), Mölnlycke Health Care and Avery Dennison Specialty Tape Division.

4. From 1997 to date I have been working with the Avery Dennison Specialty Tape Division in Turnhout Belgium, where I set up a hydrocolloid manufacturing facility and developed numerous adhesive-based materials. I continue in this capacity.

5. I have worked continuously with pressure-sensitive adhesives since about 1965. My work with hydrocolloid pressure-sensitive adhesives commenced in 1978. At Ciba-Geigy I developed new poly-α-olefin adhesives. While at J&J, I managed the project to develop new hydrocolloid adhesives in support of efforts to enter the ostomy products market. My experience

at ConvaTec as R&D Director was exclusively directed with implementation of hydrocolloid-based products into the ostomy market and the wound care market. The product DuoDerm, developed by us during 1981-2 and launched into the market in 1983, literally changed thinking on wound management and the way in which especially chronic wounds are managed.

I owned my own company, MediQuest, from 1985-96. I developed, and my company manufactured, hydrocolloid dressings for such multinational companies as Sherwood Medical (now part of Tyco) and Mölnlycke Health Care.

My work with Avery Dennison has included development of numerous new hydrocolloid adhesives including moisturizing adhesives (currently being introduced into the market as a burn dressing in Europe), and new hydrocolloids that are free of conventional tackifiers, which adhesives exhibit striking acceleration of wound healing compared to conventional hydrocolloids. These are also currently being launched into the European wound care market.

6. I am familiar with the prosecution of the present patent application. I have read the Office action dated April 5, 2004, U.S. Patent Nos. 4,231,369 (Sørensen et al.), 4,367,732 (Poulsen et al.), and 5,817,332 (Urtti et al.), and international application publication number WO 99/14282 (Avery Dennison Corporation). I am the inventor named on the latter application.

7. In the Office action dated April 5, 2004, the examiner rejected claims 1-5 and 7-16 as purportedly being obvious in view of any of the '369, '732, and '282 references taken in combination with the '332 Patent. I disagree with the examiner's conclusion that the claims are "obvious" in view of the cited references. In my professional opinion, no person of ordinary skill in the art could read the cited references and discern or infer therefrom, collectively or individually, the unique pressure-sensitive adhesive compositions claimed in the present application. My conclusion that the claims are not obvious is based on my observation of a long-felt need for an improved hydrocolloid-containing pressure-sensitive adhesive (PSA), particularly an odor-absorbent PSA, and the unexpected results obtained through the present invention, namely, striking odor absorption as compared to hydrocolloid-containing adhesives that lack cyclodextrins..

8. I am informed, and on that basis declare, that hydrocolloid adhesives were invented in 1965. I am also informed, and on that basis declare, that cyclodextrins have been known since the end of the 19th century. If the combination of the two were obvious, it surely would have been done before, given the problem of odor prevalent in both ostomy care (fecal odor) and wound care (chronic odor) -- by far the two largest uses for hydrocolloid adhesives. To my knowledge, there is but one reference -- Japanese Patent Publication JP3170575A (an English-language abstract of which is attached hereto as Exhibit B) -- in the whole of the scientific literature to an odor-absorbing adhesive. That reference refers to the absorption of the intrinsic odor, not of bodily fluids and the like, but of the adhesive components themselves. Presumably, this dearth of references reflects the mistaken belief that fecal odor and wound odor cannot be addressed by the adhesives per se, used in ostomy care and wound care.

9. There is, of course, a long-felt need for odor-absorbent materials for use in general, and odor-absorbent PSAs in particular, in ostomy care, wound care, and other applications. Despite this need, despite the fact that cyclodextrin has existed for years -- and has been used in other adhesive applications -- and despite the fact that hydrocolloids have been used in adhesives for years, the combination of the two has not heretofore been presented. In my professional opinion, this long-felt need is, in itself, compelling evidence of the nonobviousness of the claimed invention.

10. As filed, the present application includes data demonstrating the striking improvement in odor absorption achievable with the claimed invention. On pages 30-33, examples 10-12 demonstrate the odor-absorbing properties of hydrocolloid adhesives. Example 10 is a control, and contains no cyclodextrins. Each of examples 11 and 12, prepared according to the present invention, contain two or more hydrocolloids, at least one of which is a cyclodextrin.

11. As indicated in the experimental protocol described on pages 30-32, hydrocolloid pads were prepared, soaked in saline, and then inoculated with five micro liters of n-butyric acid, using a micro syringe. Butyric acid is a strong smelling compound found, together with other fatty acids, in rancid butter, rotting vegetation, and odiferous wounds. After 24 hours, the

samples were smelled in turn by four human panelists, who rated each of the three samples according to intensity of odor. The panelist smelled each jar twice, and scored each jar on a scale of 0-5, 0 being no smell and 5 being the strongest smell. The ratings of 0-5 for each adhesive (hydrocolloid pad) were rank ordered among the adhesives for each panelist, and the rankings for each adhesive were summed among the panelists. As indicated in the table on page 32 of the application, little or no odor of n-butyric acid was detected with the adhesives of examples 11 and 12, while the adhesive from example 10, which contained no cyclodextrin, retained the strong, unpleasant odor of n-butyric acid after 24 hours. These results are striking, especially when one considers that example 10 did contain a hydrocolloid, sodium carboxymethyl cellulose. The presence of cyclodextrin as a companion hydrocolloid made a substantial difference in the odor absorption characteristics of the adhesive.

12. Attached hereto as Exhibit C is a summary of a second experiment, in which the odor absorption of pure butyric acid by sodium carboxymethyl cellulose and various cyclodextrins is further put to the test. The rate of absorption of odor by cyclodextrins depends on the presence of water. The combination of cyclodextrin and a second hydrocolloid increases the rate of ingress of water into the adhesive so that it can absorb odor at a practical rate. The experiment described in Exhibit C demonstrates the dependence of odor absorption by cyclodextrins on the concentration of water. In each case, a fixed amount of n-butyric acid was added to pure, dry cyclodextrin powders contained in vials. Varying and increasing amounts of water were added to the butyric acid-inoculated cyclodextrin powders, and the absorption of butyric acid by the cyclodextrin was measured after 24 hours, using electronic nose analysis of the head space over the samples in the vials. The results clearly demonstrated that the amount of butyric acid (odor) absorbed depends on the amount of water present, for a given time elapsed. When the experiment was repeated with a hydrocolloid pressure-sensitive adhesive prepared according to the present invention (4-108A, identified in Exhibit C hereto) a similar result was obtained. The contents of the 4-108A adhesive include SIS and SI block copolymers, α-cyclodextrin, β-cyclodextrin, and sodium carboxymethyl cellulose (Aquasorb A500).

Application No. 10/069,214

13. Pressure-sensitive adhesives formulated with both a cyclodextrin and another hydrocolloid exhibit a high degree of odor absorption, as compared to PSAs that lack cyclodextrin. The synergistic combination of cyclodextrin with another hydrocolloid to provide the water needed to activate the odor-absorbing properties of the cyclodextrin is entirely new, and not obvious from the prior art.

I declare under penalty of perjury under the laws of the United States of America that all statements made herein of my own knowledge are true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

Date September 2, 2004

By _____
Roger D.A. Lipman

JDC/frs

SII PAS582478.1-*-09/1/04 4:26 PM

ROGER D.A. LIPMAN

Tichelarijstraat 54 Bus 2
B-2300 Turnhout, Belgium

Tel: 0032-14-45-23-51
Fax: 0032-14-45-23-48

OBJECTIVE

CONSULTANT with marketing oriented health care organisation, which seeks new technologies and products and where the problems call for an energetic and experienced innovator

QUALIFICATIONS

LEAD ENTREPRENEUR -MANAGING DIRECTOR with expertise and a track record in:

- setting strategic goals
- recognizing new product opportunities
- conceptualizing programs to meet goals and opportunities
- organizing the team to meet objectives
- sustaining motivation to get the job done

RESULTS

Set up hydrocolloid adhesive manufacturing unit in Turnhout, Belgium for Avery Dennison Corp and developed numerous new products protected by nine patent applications (1997-date)

Set up MediQuest Products Ltd to manufacture medical devices based on hydrocolloid adhesives. Secured contracts with two multinational groups to manufacture advanced wound care products (1986-92). Supplied 20% of new UK ostomy barrier business on OEM basis. In 1993 launched line of ostomy products in USA and achieved sales of £800,000 in 1994.

Developed package of ostomy product patents and sold these to US multinational health care group (1985-6)

Introduced an innovative business strategy for Franklin Medical Ltd, which resulted in two new product introductions in the urology sector (1983-5)

Organized for Squibb Corporation the ConvaTec division R&D Department into a functional unit that created three major new products in twelve months (Hydrocolloid Dressing, flexible ostomy flange and 1-piece ostomy device) (1981-2)

Developed for Johnson & Johnson a line of proprietary wound care products, and an improved adhesion BAND-Am Adhesive Bandage product which generated $20MM incremental sales in the US (1976-9)

The Johnson & Johnson Hoffman Research Prize was awarded to my subordinates in three successive years (1976-8)

KEY EXPERIENCE

1997-date MEDICAL DEVICE DEVELOPMENT CONSULTANCY

Full time consultant for major international adhesives manufacturer developing medical pressure sensitive adhesives

1986-96 MEDIQUEST PRODUCTS LTD, Horsham, West Sussex, England

Founder and Managing Director

Developers and manufacturers of specialized skin adhesives and medical products for the ostomy care and wound management sectors. Product and process development consultants to the medical device industry

1983-85 FRANKLIN MEDICAL LTD, High Wycombe, Bucks. England

Technical Director.

Technical and business development in anaesthesia, urology, ostomy care

1981-82 BRISTOL-MYERS SQUIBB INC, Princeton, NJ, USA

Director of R&D, ConvaTec Division

All phases of development in the business areas of ostomy care, wound management and incontinence care.

1973-80 JOHNSON AND JOHNSON, New Brunswick, NJ, USA

Manager, Adhesive Products then Manager Wound Treatment Products

Technical management/product development supporting existing and new businesses in wound management and adhesive products.

1964-73 CIBA-GEIGY CORPORATION, Ardsley, NY , USA

Chemist then Project Manager

Product and process development of products in the industrial chemicals sector – oil additives, sealants, high performance structural materials

EDUCATION

B.Sc. - Chemistry Class II(1) -Imperial College, London University, 1959
Ph.D. - Physical Chemistry -University of Cambridge, 1963
N.S.F. - Post Doctoral Research Fellow -College of Forestry, Syracuse, NY, 1963-4

PUBLICATIONS

Technical papers in the fields of catalysis, living polymers, polymerization kinetics and polymer processing. Patents on rubber tackifiers, oil additives, adhesives, adhesive bandages, wound care products, ostomy care products, hydrocolloid adhesives. Articles on physical chemistry and electrochemistry in Chambers' Encyclopaedia.

AN -1991-262350 [36]
A -[001] 01403& 03203403604- 055056117123231 244247250 25927& 303311 317329342381431442477525527 54& 541 575596597600 609 633 722 725
AP -JP19890312036 19891129 CPY -SEKI
DC -A81 G03 FS -CPI
IC -*C09J153/02*
KS -0002 0009 0222 0228 0231 0306 1102 1989 2008 2013 2266 2307 2312 2319 2436259926542674268227252780316332 52
MC -A08-MO4 A10-E14 A12-A05A G03-B02B PA -(SEKI) SEKISUI CHEM IND CO L TO
PN -JP3170575 A 19910724 DW199136 OOOpp PR -JP19890312036 19891129 XA -C1991-113814 XIC -*C09J-153/02*
AB -J03170575 Synthetic rubber tacky adhesive compsn. comprises a thermoplastic block copolymer, a tackifer resin and cyclodextrin as deodorant.
-USE/ADVANTAGE -The compsn. contains tackifier resin which imparts strong adhesive property to the adhesive but has peculiar offensive smell. The offensive odour is drastically reduced, by the cyclodextrin, so the adhesive can be used in the food field.
-In an example, an adhesive compsn. comprising 100 wt. pts. 515 block copolymer, 100 wt. pts. aliphatic tackifier resin, 50 wt. pts. naphthenic oil, 1 wt. pt. antioxidant and 3 wt. pts. (1,2 wt%) alpha-cyclodextrin was coated on kraft paper for adhesive tape to 40 micron adhesive thickness. The adhesive tape gave 1839 g/15 mm SP tacky adhesive force (JIS Z -0237-8), 8 as tackiness (steel ball used for measurement: 1132 inch in dia.), over 1440 min. retentive force and there was no bad odour in the tape at all. (5pp Dwg.No.010)
IW -SYNTHETIC RUBBER ADHESIVE COMPOSITION FOOD INDUSTRIAL COMPRISE THERMOPLASTIC BLOCK COPOLYMER TACKIFIER ALPHA CYCLODEXTRIN REDUCE OFFENSIVE ODOUR
IKW -SYNTHETIC RUBBER ADHESIVE COMPOSITION FOOD INDUSTRIAL COMPRISE THERMOPLASTIC BLOCK COPOLYMER TACKIFIER ALPHA CVCLODEXTRIN REDUCE OFFENSIVE ODOUR
NC -001
OPD -1989-11-29 ORD- 1991-07-24
PAW- (SEKI) SEKISUI CHEM IND CO LTD
TI -Synthetic rubber adhesive compsn. for e.g. food industry -comprising thermoplastic block copolymer, tackifier and alpha-cyclodex1rin to reduce offensive odour

Experiment 08/07/03 – Testing odour absorption of pure butyric acid by pure Aquasorb, α, β and γ-Cyclodextrins

08/07/03

Aim:
The purpose of this test is to check if the amount of water in the test vial has an influence on the odour absorption capacity of the cyclodextrin (containing hydrocolloid). In this experiment 5µl of pure n-butyric acid contains the same number of moles as the 2 ml of 2500ppm n-butyric acid solution used in the calibration experiments.

Set up of the experiment:

1) 2 ml each of water, 1250ppm n-butyric acid solution and 2500ppm n-butyric acid solution were pipetted into phial tubes and closed with a septum containing cap (all in triplicate). A calibration curve of electronic nose n-butyric acid response was created: => 9 samples.

2) The following test samples were prepared in triplicate:
   - 0.6 gm Aquasorb*, 0.6 gm α-CD, 0.6 gm β-CD and 0.6 gm γ-CD were weighed all in different tubes. In each tube **5µl of pure n-butyric acid + 0µl water** was added with a micropipet.
   - 0.6 gm Aquasorb, 0.6 gm α-CD, 0.6 gm β-CD and 0.6 gm γ-CD were weighed all in different tubes. In each tube **5µl of pure n-butyric acid + 5µl water** was added with a micropipet.
   - 0.6 gm Aquasorb, 0.6 gm α-CD, 0.6 gm β-CD and 0.6 gm γ-CD were weighed all in different tubes. In each tube **5µl of pure n-butyric acid + 10µl water** was added with a micropipet.
   - 0.6 gm Aquasorb, 0.6 gm α-CD, 0.6 gm β-CD and 0.6 gm γ-CD were weighed all in different tubes. In each tube **5µl of pure n-butyric acid + 100µl water** was added with a micropipet.
   - 0.6 gm Aquasorb, 0.6 gm α-CD, 0.6 gm β-CD and 0.6 gm γ-CD were weighed all in different tubes. In each tube **5µl of pure n-butyric acid + 2000µl water** was added with a micropipet.

=> measurement after 24h with the e-nose

*In the above Aquasorb refers to Aquasorb A500, the brand of sodium carboxymethyl celluose supplied by Aqualon division of Hercules Inc., and used in a number of commercially available hydrocolloid wound dressings.

CD refers to cyclodextrin generically; the specific type used appears in the results tables.

Results exp 08/07/03: absorption of pure butyric acid by pure ingredients
alpha-, beta-, gamma cyclodextrin, aquasorb and 4-108A and H-2441 + different amounts of water
results after 24h

x µl of 100% butyric + y µl of deionised water

x + y	5+0	5+5	5+10	5+100	5+2000
	%	%	%	%	%
alpha Cyclodextrin	0	70	77	79	86
beta Cyclodextrin	0	0	0	45	52
gamma Cyclodextrin	0	0	0	0	0
Aquasorb A-500, sodium CMC	0	0	0	0	0
4-108A Cyclodextrin containing hydrocolloid adhesive	0	0	0	28	80